UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI et al.,	)	
	)	
Intervenor-Plaintiffs,	)	
	)	
v.	)	Case No. 4:25-CV-1580-CMS
	)	
U.S. FOOD AND DRUG ADMINISTRATION et al.,	)	
	)	
Defendants.	)	

REPLY TO THIRD NOTICE OF SUPPLEMENTAL AUTHORITY

On May 14, 2026, the Supreme Court issued a four-sentence, "unreasoned" order staying the Fifth Circuit's decision in *Louisiana v. FDA*, 2026 WL 1194924 **(**5th Cir. 2026**)**. *Danco Laboratories, LLC v. Louisiana*, 608 U.S. __, 2026 WL 1345578, at *1 (2026) (Alito, J., dissenting). Danco Laboratories, LLC now argues that the Supreme Court's order is "a further reason that this Court should conclude the Plaintiff States lack standing" here. Doc. 238 at 2. Not so. The Supreme Court's order made no reference to Louisiana's standing and offered no explanation for staying the Fifth Circuit's order. *See Danco Laboratories*, 2026 WL 1345578. Thus, Danco's claim that the Supreme Court's order supports that the States lack standing here rests 100% upon speculation. This Court should reject Danco's invitation to ignore the basic principle of judicial review that no case—let alone a case of this magnitude and significance—should be decided upon speculation.

In any event, Plaintiffs have chosen to litigate this case quite differently than Louisiana. Whereas Louisiana simply alleged injury and sought a preliminary injunction, Plaintiffs wish to *prove* injury (and standing) through evidence. That is why Plaintiffs have not sought a preliminary injunction.

Additionally, the Supreme Court's order actually *bolsters* Plaintiffs' case in some respects. To start, "the Secretary of Health and Human Services has admitted that the FDA gave inadequate consideration to patient safety when it approved the 2023 REMS." *Id.* at *2 (Alito, J., dissenting). As the Fifth Circuit and Justice Alito have recognized, the merits are quite straightforward in this case. *Id.*; *see also Louisiana v. FDA*, No. 26-30203, 2026 WL 1194924, at *6–7 (5th Cir. May 1, 2026).

Furthermore, despite recognizing the inadequacy of the prior REMS review, "the FDA has not yet acted" upon the Secretary's announcement that "the FDA would conduct a study to determine whether changes to the REMS are needed." *Id.* "Indeed, there is evidence that that FDA leadership has told agency officials to delay that safety review for at least six months." *Id.* (citing La. App. 556). Given the FDA's apparent desire to stall, it would be highly inequitable to indefinitely stay this case while it continues doing so.

All the States want is to proceed down the normal litigation path, set appropriate briefing deadlines, and have an opportunity to be heard on claims that the States brought years ago. All of these facts demonstrate why this Court should not prolong this litigation by granting Defendants' request to indefinitely stay it.

Date: May 19, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2026, a true and accurate copy of the foregoing was electronically filed by using the Court's CM/ECF system to be served on all counsel of record entered in the case.

/s/ Louis J. Capozzi III